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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,585	08/09/2001	Paul L. Hermonat	23355/55	5438
7590	05/19/2004		EXAMINER SALIMI, ALI REZA	
J.M. (Mark) Gilbreth GILBRETH & ASSOCIATES, P.C. P.O. Box 2428 Bellaire, TX 77402-2428			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/927,585

Applicant(s)

HERMONAT ET AL.

Examiner

A R Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 16-20 and 88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 16-20 and 88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment filed 04/20/2004. Claims 1-15, 21-87, 89, and 90 have been canceled. Claims 16-20, and 88 are pending before the examiner.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Sequence Requirements***

As it was previously requested in the Office Action mailed 01/07/2003 as part of paper no.7; this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. For example see pages 44, 56. The sequences have to be identified by a specific sequence number(s).

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

***NEW MATTER***

The amendment filed 4/20/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “selectively amplify a first and second molecular marker for breast cancer”, in lines 4-5 of newly claim 16. The office has not been able to locate any teaching or reference to “molecular marker(s)” or “selectively amplify.” Applicants are respectfully requested to point to specific page and line(s) of specification wherein the limitations maybe found.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 16-20, 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. : “selectively amplify a first and second molecular marker for breast cancer”, in lines 4-5 of newly claim 16.

***Claim Rejections - 35 USC § 112***

Claims 16-20, and 88 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 10/20/2003. Applicants argue that the claimed invention is directed to method of screening a patient for cancer comprising use of SEQ ID NO: 1 and 2 in an amplification reaction. Applicants further add that they are not claiming

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nor attempting to claim, the sequences amplified by utilization of SEQ ID NO: 1 and 2.

Applicant's argument as part of Paper, filed 04/20/2004 has been considered fully, but they are not persuasive. The claims are not directed to utilization of primers SEQ ID NO: 1, and SEQ ID NO: 2. Applicants' understanding and appreciation of the scope of the main claim is misplaced. The main claim 16 does not even define the second primer. As it was indicated this rejection is directed to broad possession of any and all primers. In order to enable and teach the claimed invention applicants should be in possession of the claimed invention. The claimed invention reads on the sequences that have not been taught nor possessed, hence, the written description is lacking. The rejection is maintained.

#### **NEW GROUNDS OF REJECTION:**

##### ***Claim Rejections - 35 USC § 112***

Claims 16-20, 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite, the intended metes and bounds of the second primer is/are not defined. In addition, the claim is confusing for recitation of "designed to selectively amplify", no step is/are provided to determine the "selectivity" of the so called "technique", this is/are relative term(s), how do you determine "selectively amplify"? Moreover, the claim is vague and indefinite for recitation of "molecular marker", the intended marker is not defined. Is

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Cyclin E or Ki-67 intended? The claims have been interpreted in light of the specification, and since the specification does not provide any teaching for molecular marker the claim is vague and indefinite. Applicants are reminded that method of amplifying human papillomavirus genes from a sample by utilizing a pair of primers wherein the presence of human papillomavirus would perhaps indicate the presence of breast cancer is vastly different than the method that is now being claimed where the molecular marker of HPVs are amplified, no such teaching is present. This affects the dependent claims.

Still further, claim 16 is objected to for insertion of “..” in line 7

After SEQ ID NO: 1, appropriate correction is requested.

No claims are allowed.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

5/17/2004

ALL R. SALIMI  
PRIMARY EXAMINER